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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,752

Applicant(s)

AKIMOTO, TAIZO

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 26, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10,11 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10,11 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed March 26, 2004. Currently, claims 7-8, 10-11, 18-21 are pending.
2. Any objections and rejections not reiterated below are hereby withdrawn in view of applicants remarks and amendments to the claims.
3. This action is FINAL.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 7-8, 10-11, 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Zeleny et al (US Pat. 6,215,894, filed February 26, 1999).

In Re Donaldson, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held: The plain and unambiguous meaning of paragraph six is that one construing means- plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts

described therein, and equivalents thereof, to the extent that the specification provides such disclosure.

Zeleny et al. (herein referred to as Zeleny) teaches a system for scanning biochip arrays which includes a unique image array identifier recorded for each array, and a computer-stored record corresponding to each identifier and containing the parameters of the experiment in the array identified by the identifier (abstract). As seen in Figure 1, the microarray biochip contains two array regions and an identifier location. Figure 3, clearly illustrates the system which comprises an arrayer, a scanner, an analyzer, a computer system. Zeleny teaches that the identifier may be a number with numerals imprinted on the slide along with a bar code representation of the number (col. 2, lines 17-18). The experiment identifier is imprinted on the chip prior to the deposition of the array experiment, a means for attaching management information peculiar to the test piece to a predetermined location on the test piece (col. 2, lines 18-19). A file folder (i.e., "directory") is opened in a computer system and is logically linked to the array identifier (col. 2, lines 20-21). The folder may contain various parameters of the experiment array, e.g., a map of the reagents deposited on the array, identification of the fluorescent tags and the reagents to which they are bonded, the locations of any calibration dots on the chip, the identification of the scanning and processing protocols to be used in connection with the scanning process (col. 2, lines 23-27). Moreover, the system is programmed to retrieve the information from the biochip (col. 2, lines 30-31)(limitations of Claim 7-8). The biochip has been imprinted with experiment identifiers relating to the experiment performed in the regions. The identifiers comprise both a

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number and a corresponding bar code representation of the numeral. The identifier may be a number in which some of the digits identify experiment parameters of the array, others identify the source of the arrays, other may identify the scanning and analysis protocols or even-provide the operating parameters for those protocols, or identify the array itself (col. 3, lines 8-18). The array comprises an array of test spots, control spots and focus spots (col. 3, lines 20-22). Following the imprinting of the information on the biochip, the chips are loaded into an arrayer to deposit test spots, passed to a scanner to scan the bar codes, opens a file folder, analyzes the contents of the image maps, and generates an output table (col.3, lines 40-45).

The identifier may be a number in which some of the digits identify experiment parameters of the array, others identify the source of the arrays, others may identify the scanning and analysis protocols or even-provide the operating parameters for those protocols, and still others identify the array itself. Therefore, the management information includes, for example, the substances used as the probes.

As seen in Figure 4, the system contains a first storage means, namely a imaging system with host computer. This element decodes identification. Additionally, the system also contains means for saving image data with imaging protocols and quantitative analysis protocols, i.e. information concerning the probes (col. 3, lines 48-68).

The recitation in Claim 8 states that the management information is printed on the test piece using a marker the same as or similar to the marker used for marking the target substance. The claims are drawn to an analysis system, i.e. a product.

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Therefore, the elements of the system include a means for attaching management information to the test piece, i.e. a spotter; a means for obtaining information concerning the positions of the probes to which the target substance has bound and simultaneously detecting the management information attached to the test piece, i.e. a photomultiplier (PMT); and a means for storing the management information, i.e. a computer. The computer has several file folders as means for storing information. The claim does not require any management information, any target or any substrate. The claim does not require any particular method steps because the claim is directed to a product.

Therefore, the recitation does not impart any additional limitations on the instant claims. As seen in Figure 3, the system of Zeleny comprises a printer, an arrayer, a scanner an analyzer, an analysis program and a computer system (limitations of claim 20-21).

With respect to Claim 18-19, the claim does not require any management information. The claim is drawn to a means for attaching management information (i.e. a spotter)(see page 6 of the instant specification).

Thus, since Zeleny teaches every limitation of the claims, Zeleny anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the added limitation which states "using a marker the same as or similar to the marker used for marking the target substance" imparts function for the means for attaching and thus has patentable weight. This argument has been reviewed but is not convincing because the specification clearly provides that the pattern of the ID information may be

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attached on the test piece using a spotting device, an ink jet printer etc. (page 6). This is the means for attaching contemplated by the instant specification. Zeleny teaches a system comprising a printer. Therefore, the means for attaching management information is taught by Zeleny. The response fails to point to any aspect of the printer taught by Zeleny which is not a means for attaching management information.

Thus for the reasons above and those already of record, the rejection is maintained.

5. Claims 7-8, 10-11, 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Noblett (US Pat. 6,362,004, filed November 9, 1999).

In *Re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held: The plain and unambiguous meaning of paragraph six is that one construing means- plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure.

Noblett teaches a microarray scanning system for conducting experiments which includes an apparatus for translating the secured substrate in two axes where the substrate has at least one fiducial mark on the planar substrate as a means for positioning and aligning the substrate for subsequent spot placement, analysis or comparison procedures. Figure 2 illustrates the microarray. The microarray scanning system includes an optical system, a detector, a positioning system and a computational device, such as a computer (col. 4, lines 3-5). The microarray comprises

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a plurality of target spots, first and second fiducial marks which can be imprinted having a predetermined shape (col. 5, lines 32-40). Noblett teaches that the first fiducial mark is approximately the same size as the size of the target spot and may include the same target material forming the target spots (col. 5, lines 40-43). Noblett also teaches the use of dilution spots adjacent to the array for use in calibrating the microarray scanning system (col. 5, lines 53-55). Since the placement of the test spots was done with reference to a fiducial mark, the spot placement software can map the coordinates of the target spots relative to the fiducial mark. The stored coordinates may be placed into the memory and used to improve the accuracy or execution of subsequent procedures such as quantitation (col. 7, lines 15-20). The quantification grid for placement over the microarrays locates the precise location of all hybridized spots. The quantification grid is generated from preprogrammed parameters (e.g. spot diameter, spot spacing and array spacing) to represent an initial regular grid (col. 7, lines 50-58). Therefore, the management information, fiducial marks, are formed during the spot placement operation, the fluorescent tags obtain information as to the probes and the management information and the computer stores the information.

The fiducial mark, used to accurately and automatically align multiple images gathered by a microarray scanner from within an alignment or quantitation program, may be genetic material. The fiducial mark may comprise genetic material that responds to various materials used to test target spots. Therefore, the management information includes, for example, the position of the probes and the type of probes.

Noblett teaches that the fiducial mark comprises genetic material (col. 8, lines 20-25, see limitations of Claim 3). Noblett also teaches that probe material is labeled with fluorescent tags (col. 6, lines 34-38). .

The recitation in Claim 8 states that the management information is printed on the test piece using a marker the same as or similar to the marker used for marking the target substance. The claims are drawn to an analysis system, i.e. a product. Therefore, the elements of the system include a means for attaching management information to the test piece, i.e. a spotter; a means for obtaining information concerning the positions of the probes to which the target substance has bound and simultaneously detecting the management information attached to the test piece, i.e. a photomultiplier (PMT); and a means for storing the management information, i.e. a computer. The claim does not require any management information, any target or any substrate. The claim does not require any particular method steps because the claim is directed to a product. As seen in Figure 3, Noblett's system comprises a robotic spot placement center, a scanning system, a computational device and a program. Therefore, the recitation does not impart any additional limitations on the instant claims.

With respect to Claim 18-19, the claim does not require any management information. The claim is drawn to a means for attaching management information (i.e. a spotter)(see page 6 of the instant specification).

Thus, since Noblett teaches every limitation of the claims, Noblett anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the added limitation which states "using a marker the same as or similar to the marker used for marking the target substance" imparts function for the means for attaching and thus has patentable weight. This argument has been reviewed but is not convincing because the specification clearly provides that the pattern of the ID information may be attached on the test piece using a spotting device, an ink jet printer etc. (page 6). This is the means for attaching contemplated by the instant specification. Noblett teaches a system comprising a spotter. Therefore, the means for attaching management information is taught by Noblett. The response fails to point to any aspect of the printer taught by Noblett which is not a means for attaching management information. Thus for the reasons above and those already of record, the rejection is maintained.

6. Claims 7-8, 10-11, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Perttunen et al (US Pat. 5,968,728, October 1999).

In Re Donaldson, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held: The plain and unambiguous meaning of paragraph six is that one construing means- plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure.

Perttunen et al. (herein referred to as Perttunen) teaches a molecular detection device which includes a support member, a plurality of molecular receptors, a database, a processor, a placement apparatus and a data writing device (Figure 2, abstract). As

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seen in Figure 11 and 12, the support comprises id codes, molecular receptor sites and data. Perttunen teaches that the processor generates mappings of molecular receptors to sites of a molecular detection device. The processor may be a computer. Perttunen teaches "to deduce the molecular structures in the sample, the hybridization information is processed in conjunction with data indicating the arrangement of the molecular receptors" (col. 2, lines 40-43). The data can be stored in a database (col. 2, lines 46-47). The molecular receptors for binding or hybridizing have a predetermined structure which may include DNA probe for detecting a corresponding DNA sequence in a sample or RNA probe. Perttunen teaches that the molecular receptors can be bound to the surface using a primer, a gel or an adhesive. The apparatus also comprises a data writing device that writes data associated with the mapping directly to the support member. The data can include data which indicates or encodes the mapping and/or data which identifies the mapping. Additionally, the system includes a database which receives a signal associated with the mapping from the processor which can include an identification code for the mapping or data indicative of the mapping (col. 5, lines 7-10). Finally the support contains identification codes which allows determination that the support when separated are for the same device. The identification codes include a series of human readable printed characters or a machine-readable bar code (col. 8, lines 55-62).

The identification code identifies the mapping of the molecular receptors to the sites without revealing the mapping (col. 8, lines 8-15). The identification code can identify a record in a database having the data indicative of the mapping stored therein.

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The identification code can be include a series of letters, numbers or characters or machine readable data. Therefore, the management information includes, for example, the position of the probes and the type of probes.

The recitation of Claim 8 states that the management information is printed on the test piece using a marker the same as or similar to the marker used for marking the target substance. The claims are drawn to an analysis system, i.e. a product. Therefore, the elements of the system include a means for attaching management information to the test piece, i.e. a spotter; a means for obtaining information concerning the positions of the probes to which the target substance has bound and simultaneously detecting the management information attached to the test piece, i.e. a photomultiplier (PMT); and a means for storing the management information, i.e. a computer. The claim does not require any management information, any target or any substrate. The claim does not require any particular method steps because the claim is directed to a product. Therefore, the recitation does not impart any additional limitations on the instant claims. The system of Perttunen comprises a placement apparatus, a processor, data writing device, database and a computer.

With respect to Claim 18-19, the claim does not require any management information. The claim is drawn to a means for attaching management information (i.e. a spotter)(see page 6 of the instant specification).

Thus, since Perttunen teaches every limitation of the claims, Perttunen anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the added limitation which states "using a marker the same as or similar to the marker used for marking the target substance" imparts function for the means for attaching and thus has patentable weight. This argument has been reviewed but is not convincing because the specification clearly provides that the pattern of the ID information may be attached on the test piece using a spotting device, an ink jet printer etc. (page 6). This is the means for attaching contemplated by the instant specification. Perttunen teaches a system comprising a printer. Therefore, the means for attaching management information is taught by Perttunen. The response fails to point to any aspect of the printer taught by Perttunen which is not a means for attaching management information. Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

7. No claims allowable over the art.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeanine Goldberg
Patent Examiner
April 19, 2004



BJ FORMAN, PH.D.
PRIMARY EXAMINER